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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary**Application No.**

10/694,026

Applicant(s)

MOSBACH ET AL.

Examiner

SUE LIU

Art Unit

1639

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/4/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 23-40 is/are pending in the application.
- 4a) Of the above claim(s) 27 and 36-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 23-26 and 28-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/889,229.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/28/03
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Status

1. Claims 2-22 have been cancelled.
Claims 23-40 have been added.
Claims 1 and 23-40 are currently pending.
Claims 27 and 36-40 have been withdrawn.
Claims 1, 23-26 and 28-35 are being examined in this application.

Election/Restrictions

2. Applicant's election of Group I (1 and 23-35) in the reply filed on 12/4/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
3. Claims 36-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/4/08.
4. Applicant's election without traverse of the following species in the reply filed on 12/04/2008 is acknowledged.

The species disclosed in Example 3 of the instant specification; It is also noted applicants elected only a single type of monomer (i.e. "methacrylic acid" as described in Example 3), which

only reads on the instant claim 26 but not the instant claim 27 (which requires monomers of different functionality).

Accordingly, Claim 27 is withdrawn due to non-elected species.

Priority

5. This application claims priority benefit as a CONTINUATION of U.S. Patent Application Nos. 09/889,229 (filed 9/26/2001; which is now abandoned), which is a 371 of PCT/SE00/00047 (filed 1/13/2000).

6. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/889,229, filed on 9/26/2001.

Information Disclosure Statement

8. The IDS filed on 12/28/03 has been considered. See the attached PTO 1449 form.

9. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

10. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. MPEP 608.01.
11. Applicants are also invited to update the continuing data (benefits claimed under 35 USC 119, 120, etc.) in the first line of the specification.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34 recites “the size of the microsphere as produced is in the range of 0.01-10 μm ” which is not clear to which “size” the said phrase is referring. It is not clear if applicants are intending to refer to the “diameter” size of the microsphere or any other size. Applicants are requested to clarify.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Mosbach

15. Claims **1, 24-26** and **28-30** are rejected under **35 U.S.C. 102(b)** as being anticipated by **Mosbach et al** (WO 97/38015; 10/16/1997; cited in IDS).

The instant claims recite “A method of producing molecularly molecularly imprinted microspheres comprising specific binding sites, comprising polymerising functional monomers and crosslinkers in a reaction solvent in the presence of print molecules as templates in a surfactant-free precipitation polymerisation process, which print molecules are capable of forming non-covalent or reversible covalent interactions with said functional monomers.”

Mosbach et al, throughout the publication, teach methods of molecular imprinting using various steps and/or reagents (e.g. Abstract). The reference teaches polymerizing functional monomers (such as MAA) with crosslinkers (such as EDMA) in the presence of various molecules (such as cortisol) using a surfactant free solvent (a dry porogen such as acetone) (e.g. pp.9-10), which read on the instant claimed method as recited in **clm 1**. The reference also teaches the reaction allows the formation of “non-covalent” bonds between the monomer and the printed molecule.

The reference also teaches various crosslinkers can be used (such as TRIM) (e.g. p.7, line 15), which read on the elected species of TRIM.

The reference also teaches crushing and grounding the formed polymer (e.g. p.9, lines 24+), which the act of crushing and grounding would necessarily form “microspheres” as recited in **clm 1**.

The reference also teaches sedimentation in acetone (e.g. p.9, lines 26+), which the process of polymerization and sedimentation read on the “precipitation polymerization process” as recited in **clm 1**. It is also an inherent property of polymerization reaction conducted in acetonitrile to precipitate out of solution as the polymer chains grow to a critical chain length, as evidenced by Li et al. (e.g. p.3258) (Journal of Polymer Science: Part A: Polymer Chemistry. Vol.31: 3257-3263; 1993; cited in IDS).

The reference teaches using acetone (e.g. p.9), which reads on the non-aqueous solution of **clms 24 and 25**.

The reference teaches forming a polymer comprised of only MAA monomers (e.g. pp.9+), which reads on the monomer with the same functionality as recited in **clm 26**.

The reference also teaches modifying the concentration of the print molecules in the solvent to increase solubility (e.g. p.8), which read on the solubility of **clm 28**.

The reference teaches using at least UV for the polymerization reaction (e.g. p.9, lines 15+), which read on **clm 29**.

The polymerization reaction of the reference also read on **clm 30**.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Mosbach and Li

18. Claims 1, 23-26 and 28-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Mosbach** et al (WO 97/38015; 10/16/1997; cited in IDS), in view of **Li** et al. (Journal of Polymer Science: Part A: Polymer Chemistry. Vol.31: 3257-3263; 1993; cited in IDS).

Mosbach et al, throughout the publication, teach methods of molecular imprinting using various steps and/or reagents, as discussed *supra*. The teachings of Mosbach et al., as discussed *supra*, are hereby incorporated by reference in its entirety.

Mosbach et al. do not explicitly teach the total volume of the monomer and crosslinker is about 0.01 to 20% of the reaction solvent volume as recited in **clm 23**. The reference also does not explicitly teach controlling the nucleation and particle growth process by adjusting the reaction composition/condition to produce monodispersed microspheres as recited in **clms 31-35**.

However, Li et al. throughout the publication, teach synthesis of monodisperse microspheres (e.g. Abstract). The reference teaches using 2 vol % of monomer and crosslinker relative to total volume of solvent (such as acetonitrile) (e.g. p.3258, para 2). The reference also teaches varying the monomer, crosslinker and/or initiator (for nucleation) concentrations in the reaction, for examples, to change the particle morphology (e.g. p.3259; Table 1; p.3260; Table II). The reference also teaches the said changes in the reaction composition/condition allow the production of microspheres with various sizes (e.g. Tables). The reference also teaches changes in the solubility of the formed polymers (e.g. Tables). The reference also teaches the intended use or inherent property of avoiding aggregation (e.g. Abstract). The reference also teaches various particle sizes can be formed include 3.6 μm in diameter (e.g. Table II).

Therefore, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to conduct a MIP reaction with the appropriate reactant (monomer + crosslinker) to solvent ratio (such as 0.01-20% in volume) as well as varying the reaction composition/condition to generate polymers with desired morphology, size and/or properties .

A person of ordinary skill in the art would have been motivated at the time of the invention to use the appropriate reactant (monomer + crosslinker) to solvent ratio, because Li et al. teach it is routine and known to use the right amount of solvent so that the reactant are dissolved in the solvent. In addition, because both the Mosbach reference and Li reference teach methods of making polymers from monomers using similar reactant/solvents for various purposes, it would have been obvious to one skilled in the art to substitute reactant-solvent ratio

for the other to achieve the predictable result of generating desired polymers using monomers in appropriate amount of solvent.

A person of ordinary skill in the art would have been motivated at the time of the invention to vary the reaction composition/conditions (including changing the concentrations of monomer, crosslinker, initiator, or solvent composition) to produce the desired polymers, because Li et al. teach it is routine and known to produce polymers of various morphology (such monodisperse microsphere), sizes, or other properties by varying the reaction composition/conditions. Li et al. also teach the advantages of altering the reaction composition/condition so that stable monodisperse microspheres with altered solubility can be produced that are “stabilizer free” (e.g. Abstract; p.3262). Thus, it would have been obvious to one of ordinary skill in the art to apply the standard technique of varying polymerization conditions as taught by Li et al, to improve the polymerization reaction for the predictable result of enabling standard molecular imprinting reaction for the production of imprinted polymers in monodisperse microsphere morphology.

A person of ordinary skill in the art would have reasonable expectation of success of achieving such modifications since Mosbach et al. and Li et al have demonstrated the success of generating various polymers using various chemical reactants and solvents.

Mosbach, Li and Rachkov

19. Claims 1, 23-26 and 28-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Mosbach** et al (WO 97/38015; 10/16/1997; cited in IDS), in view of **Li** et al. (Journal of

Polymer Science: Part A: Polymer Chemistry. Vol.31: 3257-3263; 1993; cited in IDS), and further in view of **Rachkov** et al (Polymers for Advanced Technologies. Vol. 9: 511-519; 1998).

Mosbach et al, throughout the publication, teach methods of molecular imprinting using various steps and/or reagents, as discussed supra.

Li et al. throughout the publication, teach synthesis of monodisperse microspheres, as discussed supra.

The combined teachings of **Mosbach** et al. and **Li** et al., as discussed supra, are hereby incorporated by reference in its entirety.

The combination of **Mosbach** and **Li** does not explicitly teach imprinted molecules is “ β -estradiol” as the elected species by applicants.

However, **Rochkov** et al., throughout the publication, teaches methods of using molecular imprinting to create artificial receptors for β -estradiol (e.g. Abstract). The reference teaches the need to develop polymers that can recognize steroids compounds such as β -estradiol so that the molecular recognition can be studied for various applications for biotechnology, medicine, environmental control, etc.

Therefore, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to use make polymers that recognize β -estradiol using molecular imprinting techniques.

A person of ordinary skill in the art would have been motivated at the time of the invention to use β -estradiol as the template for MIP, because **Rachkov** et al. teach it is routine and known to using steroids such as β -estradiol as templates and the needs to develop artificial receptor for β -E so that various practical applications can be developed. In addition, because all

of the cited references teach methods of making polymers from monomers using similar reactant/solvents and templates for various purposes, it would have been obvious to one skilled in the art to substitute one template (the imprinted molecule) for the other to achieve the predictable result of generating desired polymers using the template (printing molecule) of interest.

A person of ordinary skill in the art would have reasonable expectation of success of achieving such modifications since all the cited references have demonstrated the success of generating various polymers using various templates and/or chemical reactants/solvents.

Double Patenting

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

'418

21. Claims 1, 26 and 30-35 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,489,418 (hereinafter referred to as '418 patent) in view of Li et al. (Journal of Polymer Science: Part A: Polymer Chemistry, Vol.31: 3257-3263; 1993; cited in IDS).

The '418 patent claims methods of molecular imprinting using various steps/reagents (e.g. claim 1).

The '418 patent also claims polymerizing monomers with crosslinkers in the presence of a molecule to form matrix (e.g. claim 1).

The '418 patent does not explicitly claim making microspheres using a surfactant-free solvent as recited in the instant claim 1.

However, Li et al. throughout the publication, teach synthesis of monodisperse microspheres (e.g. Abstract). The reference teaches using 2 vol % of monomer and crosslinker relative to total volume of solvent (such as acetonitrile) (e.g. p.3258, para 2). The reference also teaches varying the monomer, crosslinker and/or initiator (for nucleation) concentrations in the reaction, for examples, to change the particle morphology (e.g. p.3259; Table I; p.3260; Table II). The reference also teaches the said changes in the reaction composition/condition allow the production of microspheres with various sizes (e.g. Tables). The reference also teaches changes in the solubility of the formed polymers (e.g. Tables). The reference also teaches the intended use or inherent property of avoiding aggregation (e.g. Abstract). The reference also teaches various particle sizes can be formed include 3.6 μm in diameter (e.g. Table II).

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to conduct a MIP reaction with the appropriate reactant (monomer + crosslinker) to solvent ratio (such as 0.01-20% in volume) as well as varying the reaction composition/condition to generate polymers with desired morphology, size and/or properties .

A person of ordinary skill in the art would have been motivated at the time of the invention to use the appropriate reactant (monomer + crosslinker) to solvent ratio, because Li et al. teach it is routine and known to use the right amount of solvent so that the reactant are dissolved in the solvent. In addition, because both the '418 patent and Li reference teach methods of making polymers from monomers using similar reactant/solvents for various purposes, it would have been obvious to one skilled in the art to substitute reactant-solvent ratio for the other to achieve the predictable result of generating desired polymers using monomers in appropriate amount of solvent.

A person of ordinary skill in the art would have been motivated at the time of the invention to vary the reaction composition/conditions (including changing the concentrations of monomer, crosslinker, initiator, or solvent composition) to produce the desired polymers, because Li et al. teach it is routine and known to produce polymers of various morphology (such monodisperse microsphere), sizes, or other properties by varying the reaction composition/conditions. Li et al. also teach the advantages of altering the reaction composition/condition so that stable monodisperse microspheres with altered solubility can be produced that are "stabilizer free" (e.g. Abstract; p.3262). Thus, it would have been obvious to one of ordinary skill in the art to apply the standard technique of varying polymerization

conditions as taught by Li et al, to improve the polymerization reaction for the predicable result of enabling standard molecular imprinting reaction for the production of imprinted polymers in monodisperse microsphere morphology.

A person of ordinary skill in the art would have reasonable expectation of success of achieving such modifications since the '418 patent and Li et al have demonstrated the success of generating various polymers using various chemical reactants and solvents.

'461

22. Claims 1, 26 and 30-35 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,255,461 (hereinafter referred to as '461 patent) in view of Li et al. (Journal of Polymer Science: Part A: Polymer Chemistry, Vol.31: 3257-3263; 1993; cited in IDS).

The '461 patent claims methods of molecular imprinting using various steps/reagents (e.g. claim 6).

The '461 patent also claims polymerizing monomers with crosslinkers in the presence of a molecule to form matrix (e.g. claim 6).

The '461 patent does not explicitly claim making microspheres using a surfactant-free solvent as recited in the instant claim 1.

However, Li et al. throughout the publication, teach synthesis of monodisperse microspheres (e.g. Abstract). The reference teaches using 2 vol % of monomer and crosslinker relative to total volume of solvent (such as acetonitrile) (e.g. p.3258, para 2). The reference also teaches varying the monomer, crosslinker and/or initiator (for nucleation) concentrations in the

reaction, for examples, to change the particle morphology (e.g. p.3259; Table 1; p.3260; Table II). The reference also teaches the said changes in the reaction composition/condition allow the production of microspheres with various sizes (e.g. Tables). The reference also teaches changes in the solubility of the formed polymers (e.g. Tables). The reference also teaches the intended use or inherent property of avoiding aggregation (e.g. Abstract). The reference also teaches various particle sizes can be formed include 3.6 μm in diameter (e.g. Table II).

Therefore, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to conduct a MIP reaction with the appropriate reactant (monomer + crossliner) to solvent ratio (such as 0.01-20% in volume) as well as varying the reaction composition/condition to generate polymers with desired morphology, size and/or properties .

A person of ordinary skill in the art would have been motivated at the time of the invention to use the appropriate reactant (monomer + crossliner) to solvent ratio, because Li et al. teach it is routine and known to use the right amount of solvent so that the reactant are dissolved in the solvent. In addition, because both the '461 patent and Li reference teach methods of making polymers from monomers using similar reactant/solvents for various purposes, it would have been obvious to one skilled in the art to substitute reactant-solvent ratio for the other to achieve the predictable result of generating desired polymers using monomers in appropriate amount of solvent.

A person of ordinary skill in the art would have been motivated at the time of the invention to vary the reaction composition/conditions (including changing the concentrations of monomer, crosslinker, initiator, or solvent composition) to produce the desired polymers,

because Li et al. teach it is routine and known to produce polymers of various morphology (such monodisperse microsphere), sizes, or other properties by varying the reaction composition/conditions. Li et al. also teach the advantages of altering the reaction composition/condition so that stable monodisperse microspheres with altered solubility can be produced that are “stabilizer free” (e.g. Abstract; p.3262). Thus, it would have been obvious to one of ordinary skill in the art to apply the standard technique of varying polymerization conditions as taught by Li et al, to improve the polymerization reaction for the predictable result of enabling standard molecular imprinting reaction for the production of imprinted polymers in monodisperse microsphere morphology.

A person of ordinary skill in the art would have reasonable expectation of success of achieving such modifications since the ‘461 patent and Li et al have demonstrated the success of generating various polymers using various chemical reactants and solvents.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sue Liu/
Primary Examiner, AU 1639
3/22/09